DETAILED ACTION

- Receipt is acknowledged of applicants' RCE and remarks, filed on 7 April 2010.
- Applicants' remarks have been considered but are moot in view of the new grounds of rejection.

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Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7 April 2010 has been entered.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1-5 and 7-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,780,047 ("Kamiya") in view of JP 2000 212074 ("Sato") (cited on the IDS filed on 29 January 2003).

Kamiya discloses a device for delivering at least one active agent to a localized body surface (*see* col. 1, lines 4-12) comprising:

- the cold water-soluble carrier of instant claim 1 (*see* col. 2, lines 14-49);
- the cold water-soluble adhesive of instant claim 1 (*see* col. 4, line 36);
- the support layer of instant claim 1 (*see* col. 10, line 44);
- the nonwoven fabric of instant claim 2 (*see* col. 6, line 2);
- the monomers of instant claim 3 (*see* col. 4, line 12);
- the polyvinyl alcohol of instant claim 4 (*see* col. 3, lines 7-8);
- the gelatin of instant claim 5 (*see* col. 4, line 41);
- the alkyl ether ethoxylate (phenylethyl alcohol) of instant claim 8 (*see* col. 7, line 35);
- the pressure sensitive adhesive of instant claim 10 (*see* col. 10, lines 30-43);
- the cold water-soluble polymer of instant claim 11 (*see* col. 3, lines 7-8);
- the plasticizer (sorbitol) of instant claim 11 (*see* col. 5, line 11);
- the water-soluble monomer of instant claim 12 (*see* col. 4, line 12);
- the polysaccharide of instant claim 13 (*see* col. 3, line 24);
- the polymeric film of instant claim 14 (*see* col. 6, lines 35-44);
- the cold water-soluble carrier of instant claim 15 (*see* col. 2, lines 14-49);
- the cold water-soluble adhesive of instant claim 15 (*see* col. 4, line 36);
- the support layer of instant claim 15 (*see* col. 10, line 44);
- the active agent effective for treatment of skin of instant claim 16 (*see* col. 1, line 7);

- the dye of instant claim 17 (*see* col. 7, line 54);
- the sodium monophosphate (sodium phosphate) of instant claim 18 (*see* col. 7, line 7);
- the appliqué (pigment) of instant claim 19 (see claim 11);
- the perfume of instant claim 20 (*see* claim 11);
- the deodorant (perfume) of instant claim 21 (*see* claim 11);
- the drug of instant claims 22, 23, and 25 (*see* col. 7, line 16);
- the nonwoven fabric of instant claim 29 (*see* col. 6, line 2);
- the monomers of instant claim 30 (*see* col. 4, line 12);
- the polyvinyl alcohol of instant claim 31 (*see* col. 3, lines 7-8);
- the monohydric alcohol (phenylethyl alcohol) of instant claim 32 (*see* col. 7, line 35);
- the alkyl ether ethoxylate (phenylethyl alcohol) of instant claim 33 (*see* col. 7, line 35);
- the pressure sensitive adhesive of instant claim 35 (*see* col. 10, lines 30-43);
- the cold water-soluble polymer of instant claim 36 (*see* col. 3, lines 7-8);
- the plasticizer (sorbitol) of instant claim 36 (*see* col. 5, line 11);
- the water-soluble monomer of instant claim 37 (*see* col. 4, line 12);
- the polysaccharide of instant claim 38 (*see* col. 3, line 24);
- the polymeric film of instant claim 39 (*see* col. 5, line 40).

Two water-soluble layers may be lined with a releasable support layer (see col. 6, lines 35-44).

The coating, dissolving, suspending, and emulsifying processes of claims 24, 25, 27, and 28 are not essential to a determination of patentability of the system disclosed in the claim. The patentability of product-by-process claims is based on the product itself. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Kamiya explains that the disclosed device is beneficial because it, "...can exert excellent effects of relieving topical symptoms of a human body." *See* col. 2, lines 15-16.

Kamiya differs from the instant application in that it does not teach a carrier comprising a plasticizer.

Sato teaches a multilayer pressure sensitive gel-structure sheet comprising an adhesive layer and a base layer (analogous to the carrier of the instant application) (see claim 1). The gel of the base layer may comprise a polymer such as a vinyl pyrrolidone (see [0014] and [0022]) or polyvinyl alcohol (see [0022]). A textile or nonwoven fabric (analogous to the support layer of the instant application) may be added to the inside (i.e. base layer side) of the pressure sensitive adhesive (see [0014], [0041], and [0042]). A plastic film (analogous to the support layer of the instant application) may also be applied to the base layer surface (see [0061]). These configurations result in a

support/carrier/adhesive structure. The gel base layer may further comprise active agents, such as cosmetics or drugs (see [0018] and [0045]) and plasticizers, such as polyhydric alcohols (see [0018], [0026], and [0047]). Sato explains that such plasticizers are beneficial as moisturizers (see [0047]).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a device for delivering at least one active agent to a localized body surface comprising a cold water-soluble carrier (further comprising a polymer and a plasticizer), a cold water soluble adhesive, and a support layer, as taught by Kamiya in view of Sato. One of ordinary skill in the art at the time the invention was made would have been motivated to add a plasticizer to the carrier because it acts as a moisturizer, as explained by Sato (see above).

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2. Claims 1 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,780,047 ("Kamiya") in view of JP 2000 212074 ("Sato") (cited on the IDS filed on 29 January 2003) further in view of U.S. Patent No. 5,028,435 ("Katz").

Kamiya and Sato are discussed above.

Kamiya explains that the disclosed device is beneficial because it, "...can exert excellent effects of relieving topical symptoms of a human body." *See* col. 2, lines 15-16.

The Kamiya reference differs from the instant case in that it does not teach the arabinogalactan of instant claim 6.

Katz, et. al. teach use of a protein and a carbohydrate in a transdermal system.

Katz, et. al disclose a transdermal delivery system comprising a backing having a matrix layer which incorporates a drug and a percutaneous enhancer for the drug. At least one of the drug and enhancer is contained within a plurality of polymeric particles dispersed throughout the matrix layer (*see* col. 3, lines 58-62). The particles may be formed using natural polymers such as arabinogalactan (*see* col. 7, lines 28-32).

Katz, et. al. explain that polymers such as arabinogalactan and gelatin are useful because they contribute to the stability of the transdermal drug delivery device, as well as to a long shelf life for the device (*see* col. 7, lines 14-19).

Thus, it would have been obvious for one of ordinary skill in the art at the time of the invention to add a protein, such as collagen, and a carbohydrate, such as arabinogalactan to a transdermal delivery device, as taught by Kamiya in view of Katz, et. al. Motivation to do so, as explained above, would come from increased stability and longer self life of the device.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner, Art Unit 1615

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